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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,342	04/25/2001	Bruce L. Roberts	GA0211US	8525

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EXAMINER	
DECLOUX, AMY M	
ART UNIT	**PAPER NUMBER**
1644	5

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/843,342	Applicant(s) ROBERTS ET AL.	
	Examiner Amy M. DeCloux	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a method for inducing an immune response to an endogenous antigen comprising delivering a cytotoxic agent that stimulates in vivo loading of an endogenous antigen into an antigenic binding protein molecule so that the endogenous antigen is preresented to a T cell and the agent induces lysis of a target cell, classified in class 424, subclass 184.1.

II. Claims 2-3, drawn to a method for inducing lysis of a target cell in a subject comprising inducing an immune response to an exogenous rejection antigen and delivering to a target cell a polynucleotide encoding the exogenous antigen, classified in class 424, subclass 184.1.

III. Claims 4-6, drawn to a fusion protein comprising a T cell antigen presenting domain to an oligomerization domain, classified in class 424, subclass 192.1.

IV. Claims 7-11, drawn to an isolated polynucleotide encoding a fusion protein , classified in class 435, subclass 69.7.

V. Claim 12, drawn to a method of producing an antigen presenting multimer comprsing the isolated polynucleotide of claim 7, classified in class 435, subclass 69.1.

VI. Claims 13-14, drawn to a method of detecting an antigen specific T cell comprising antigen presenting multimers of claim 12, classified in class 435, subclass 7.21.

VII. Claim 15, drawn to a T cell, classified in class 435, subclass 325.

VIII. Claim 16, drawn to a method of expanding a population of antigen specific T cells comprising the cell of claim 15, classified in class 435, subclass 7.2.

IX. Claim 17, drawn to The T cell population expanded by the method of claim 16, classified in class 435, subclass 325.

X. Claim 18, drawn to a method of enhancing an immune response comprising administering to a subject an expanded population of antigen specific T cells of claim 17, classified in class 424, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I/II/V/VI/VIII, are unique methods. The methods of Groups , I/II, V, VII and X contain distinct endpoints and associated process steps. Though the endpoints of Groups I and II are identical, the process steps differ. Therefore, Groups I/II/V/VI/VIII are patentably distinct, each from the other.

Groups III/IV/VII/IX are unique products. Groups III, IV and VII/IX differ with respect to their structure and biochemical /physicochemical properties, being drawn to protein, nucleic acid and cells, respectively. Though both groups VII and IX encompass cellular material, the former comprises one cell, while the latter group comprises a population of cells which due to

random mutation rates, will not be homogenous. Therefore Groups III/IV/VII/IX are patentably distinct.

Groups IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the polynucleotide encoding the fusion protein, can be used as an immunogen in a method of producing monoclonal antibodies, as well as in a method of producing an antigen presenting multimer.

Groups VI and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the T cell, can be made/isolated by panning with the fusion protein encoded by the polynucleotide, as well as in a method comprising antigen presenting multimers.

Groups VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the T cell, can be used as an immunogen in a method of producing monoclonal antibodies, as well as in a method of expanding a population of antigen specific T cells.

Groups IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the T cell population, can be used as an immunogen in a method of producing monoclonal antibodies, as well as in a method of enhancing an immune response.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, PhD,
Patent Examiner, Group 1640,
June 30, 2002

amy DeCloux 7-1-02